ForPatients
*by Roche*

Macular DegenerationAge-Related Macular DegenerationGeographic Atrophy

# Testing a new medicine (galegenimab) to find out if it is effective for a type of eye disease (geographic atrophy secondary to age-related macular degeneration)

A Study Assessing the Safety, Tolerability, and Efficacy of RO7171009 in Participants With Geographic Atrophy Secondary to Age-Related Macular Degeneration (AMD)

| Trial Status | Trial Runs In | Trial Identifier |
|---|---|---|
| Terminated | 1 Country | NCT03972709 GR40973 |

*The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.*

## *Official Title:*

A Phase II, Multicenter, Randomized, Single-Masked, Sham-Controlled Study to Assess Safety, Tolerability, and Efficacy of Intravitreal Injections of FHTR2163 in Patients With Geographic Atrophy Secondary to Age-Related Macular Degeneration (GALLEGO)

## *Trial Summary:*

This clinical trial was done to find out if a new medicine called, “galegenimab,” was effective for the treatment of patients with a type of eye disease (geographic atrophy [GA] secondary to age-related macular degeneration [AMD]). This was a phase 2, randomized, sham-controlled study to assess the efficacy, safety, and tolerability of eye injections (intravitreal injections) given to patients with GA secondary to AMD. The study took place at 77 study centers at 71 study sites in one country – the USA.

| Genentech, Inc. (A part of F. Hoffmann-La Roche Ltd., Switzerland) | Phase 2 |
|---|---|
| Sponsor | Phase |

**NCT03972709 GR40973**
Trial Identifiers

## *Eligibility Criteria:*

| Gender | Age | Healthy Volunteers |
|---|---|---|
| All | #60 Years | No |

## *Inclusion Criteria:*

- Age >/= 60 years at time of signing Informed Consent Form;
- Visual acuity: best-corrected visual acuity (BCVA) letter score >/= 24 letters (Snellen equivalent of 20/320 or better). If the study eye BCVA letter score is >/= 69 letters (Snellen equivalent of 20/40 or better), the non-study eye must have a BCVA letter score of >/= 44 letters (Snellen equivalent of 20/125 or better);
- Well-demarcated area of GA secondary to AMD with no evidence of prior or active choroidal neovascularization (CNV) in either eye.

## *Exclusion Criteria:*

Ocular Exclusion Criteria, Study Eye:

- History of vitrectomy surgery, submacular surgery, or any surgical intervention for AMD;
- Previous laser photocoagulation or ITV anti-vascular endothelial growth factor (anti-VEGF) for CNV, diabetic macular edema, retinal vein occlusion, or proliferative diabetic retinopathy.

Ocular Exclusion Criteria, Both Eyes:

- GA in either eye due to causes other than AMD;
- Active uveitis and/or vitritis (grade trace or above) in either eye;
- Active, infectious conjunctivitis, keratitis, scleritis, or endophthalmitis in either eye;
- Retinal pigment epithelium (RPE) tear that involves the macula in either eye;
- Previous participation in interventional clinical trials for GA or dry AMD, except for vitamins and minerals, regardless of the route of administration (i.e., ocular or systemic) within the last 6 months.